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OFFICIAL GAZETTE



GOVERNMENT OF GOA

EXTRAORDINARY

GOVERNMENT OF GOA

Law (Legal and Legislative Affairs) Department

Notification

12-1-94/LA

The following Notification received from the Government of India, Ministry of Health and Family Welfare, New Delhi bearing No. S. 12011/2/94-ms dated 4th February, 1995 is hereby published for the general information of the public.

P. V. Kadnekar, Joint Secretary (Law).

Panaji, 18th August, 1995.

MINISTRY OF HEALTH AND FAMILY WELFARE

Notification

New Delhi, the 4th February, 1995

S. O. 80 (E).— In exercise of the powers conferred by sub-section (3) of section 1 of the Transplantation of Human Organs Act, 1994 (42 of 1994), the Central Government hereby appoints the Fourth day of February, 1995, as the date on which the said Act shall come into force in the States of Goa, Himachal Pradesh and Maharashtra and in all the Union territories.

[No. S. 12011/2/94-MS]

O. P. NIGAM
Chief Controller of Accounts

Notification

12-1-94/LA

The following Notification received from the Government of India, Ministry of Health and Family Welfare, New Delhi dated 4th February, 1995 is hereby published for the general information of the public.

P. V. Kadnekar, Joint Secretary (Law).

Panaji, 18th August, 1995.

MINISTRY OF HEALTH & FAMILY WELFARE

Notification

New Delhi, the 4th February, 1995

G. S. R. 51 (E).— In exercise of the powers conferred by sub-section (1) of Section 24 of the Transplantation of Human Organs Act, 1994 (42 of 1994), the Central Government hereby makes the following rules, namely:—

1. *Short title and commencement.*— (1) These rules may be called the Transplantation of Human Organs Rules, 1995.

(2) They shall come into force on the date of their publication in the Official Gazette.

2. *Definitions.*— (a) "Act" means the Transplantation of Human Organs Act, 1994 (42 of 1994);

(b) "Form" means a form annexed to these Rules;

(c) "Section" means a section of the Act;

(d) words and expressions used and not defined in these Rules, but defined in the Act, shall have the same meanings respectively assigned to them in the Act.

3. *Authority for Removal of Human Organ.*— Any donor may authorise the removal, before his death, of any human organ of his body for therapeutic purposes in the manner and on such conditions as specified in Form 1.

4. *Duties of the Medical Practitioner.*— (1) A registered medical practitioner shall, before removing a human organ from the body of a donor before his death satisfy himself—

(a) that the donor has given his authorisation in Form 1;

(b) that the donor is in proper state of health and is fit to donate the organ, and shall sign a certificate as specified in Form 2.

(c) that the donor is a near relative of the recipient, and shall sign a certificate as specified in Form 3 after carrying out the following tests on the donor and the recipient, namely:—

(i) tests for the antigenic products of the Human Major Histocompatibility system HLA-A, HLA-B and HLA-DR using conventional serological techniques;

(ii) tests to establish HLA-DR beta and HLADQ beta gene restriction fragment length polymorphism;

(iii) where the tests referred to in sub-clause (i) and sub-clause (ii) do not establish a genetic relationship between the donor and the recipient, tests to establish DNA polymorphisms using at least two multi-locus gene probe;

(iv) where the tests referred to in sub-clause (iii) do not establish a genetic relationship between the donor and the recipient further tests to establish DNA polymorphisms using at least five single locus polymorphic probes.

(d) in case recipient is a spouse of the donor, record the statements of the recipient and the donor to the effect that are so related and shall sign a certificate in Form 4.

(2) A registered medical practitioner shall, before removing a human organ from the body of a person after his death satisfy himself—

(a) that the donor had, in the presence of two or more witnesses (at least one of whom is a near relative of such person), unequivocally authorised as specified in Form 5 before his death, the removal of the human organ of his body, after his death, for therapeutic purposes and there is no reason to believe that the donor had subsequently revoked the authority aforesaid;

(b) that the person lawfully in possession of the dead body has signed a certificate as specified in Form 6 or Form 7.

(3) A registered medical practitioner shall, before removing a human organ from the body of a person in the event of his brain-stem death, satisfy himself—

(a) that a certificate as specified in Form 8 has been signed by all the members of the Board of medical experts referred to in sub-section (6) of section 3 of the Act;

(b) that in the case of brain-stem death of a person of less than eighteen years of age, a certificate specified in Form 8 has been signed by all the members of the Board of medical experts referred to in sub-section (6) of section 3 of the Act and an authority as specified in Form 9 has been signed by either of the parents of such person.

5. *Preservation of Organs.*— The organ removed shall be preserved according to current and accepted scientific methods in order to ensure viability for the purpose of transplantation.

6. The donor and the recipient shall make jointly an application to grant approval for removal and transplantation of a human organ, to the Authorisation Committee as specified in Form 10.

7. *Registration of Hospital.*— (1) An application for registration shall be made to the Appropriate Authority as specified in Form 11. The application shall be accompanied by a fee of rupees one thousand payable to the Appropriate Authority by means of a bank draft or postal order.

(2) The Appropriate Authority shall, after holding an inquiry and after satisfying itself that the applicant has complied with all the requirements, grant a certificate of registration as specified in Form 12 and shall be valid for a period of five years from the date of its issue and shall be renewable.

8. *Renewal of Registration.*— (1) An application for the renewal of a certificate of registration shall be made to the Appropriate Authority within a period of three months prior to the date

of expiry of the original certificate of registration and shall be accompanied by a fee of rupees five hundred payable to the Appropriate Authority by means of a bank draft or postal order.

(2) A renewal certificate of registration shall be as specified in Form 13 and shall be valid for a period of five years.

(3) If, after an inquiry including inspection of the hospital and scrutiny of its past performance and after giving an opportunity to the applicant, the Appropriate Authority is satisfied that the applicant, since grant of certificate of registration under sub-rule (2) of Rule 7 has not complied with the requirements of this Act and the Rules made thereunder and conditions subject to which the certificate of registration has been granted, shall, for reasons to be recorded in writing, refuse to grant renewal of the certificate of registration.

9. *Conditions for grant of certificate of registration.*— No hospital shall be granted a certificate of registration under this Act unless it fulfills the following requirement of manpower, equipment, specialised services and facilities as laid down below:—

GENERAL REQUIREMENT:

1. Surgical Staff
2. Cardiology Staff
3. Nursing Staff
4. Communication System
5. Intensivist
6. Medical Social Welfare
7. Perfusionist

VARIOUS DEPARTMENTS:

1. Microbiology
2. Mycology
3. Pathology
4. Virology
5. Nephrology
6. Neurology
7. Psychology
8. G. I. Surgery
9. Anaesthesiology
10. Imaging Facilities
11. Paediatrics
12. Physiotherapy
13. Immunology
14. Haematology
15. Blood Bank
16. Clinical Chemistry
17. Cardiology

NON-TRANSPLANTATION PROGRAMME TEAM:

1. Neurologist
2. Neurosurgeon
3. Medical Superintendent
4. And Other Hospital Staff

BASIC EQUIPMENT

Operating Room facilities for routine open heart surgery which includes heart lung machine and accessories.

ADDITIONAL EQUIPMENT REQUIRED FOR TRANSPLANTATION PROGRAMME

1. Cell Saver
2. Assist devices like IABP, Centrifugal Pump and various assist devices, both pneumatic and electric operated.
3. Mobile C-arm, image intensifier for routine biopsies in the sterile operating room.

4. Eact/Alert System for early detection of any infection.
5. Radioimmunoassay for measuring Cyclosporin levels.
6. Routine Laboratory facilities for detection of HIV, Australia antigen, CMV, Toxoplasmosis and other Mycology Tests.

EXPERTS

(A) Kidney Transplantation:

M. S. (Gen.) Surgery or equivalent qualification with three years post M. S. training in a recognised centre in India or abroad and having attended to adequate number of renal transplantation as an active member of team.

(B) Transplantation of Liver & Other Abdominal Organs:

M. S. (Gen.) Surgery or equivalent qualification with adequate post M. S. training in an established centre with a reasonable experience of performing liver transplantation as an active member of team.

(C) Cardiac, Pulmonary, Cardio-Pulmonary Transplantation:

M. Ch. Cardio-thoracic and vascular surgery or equivalent qualification in India or abroad with at least 3 years experience

as an active member of the team performing an adequate number of open heart operations per year and well-versed with Coronary by-pass surgery and Heart-Valve surgery.

10. APPEAL

(1) Any person aggrieved by an order of the Authorisation Committee under sub-section (6) of section 9, or by an order of the Appropriate Authority under sub-section (2) of section 15 and Section 16 of the Act, may, within thirty days from the date of receipt of the order, prefer an appeal to the Central Government.

(2) Every appeal shall be in writing and shall be accompanied by a copy of the order appealed against.

[F. No. S. 12011/2/94-MS]

O. P. NIGAM

Chief Controller of Accounts

FORM - 1
(See rule 3)

I,, aged s/o, d/o, w/o, Mr resident of hereby authorised to remove for therapeutic purposes/consent to donate my organ, namely, to:

(i) Mr./Mrs. s/o, d/o, w/o, Mr. aged resident of who happens to be my near relative as defined in clause (i) of section 2 of the Act.

OR

(ii) Mr./Mrs. s/o, d/o, w/o, Mr. aged resident of towards whom I possess special affection or attachments, or for any special reason (to be specified).

I certify that the above authority/consent has been given by me out of my own free will without any under pressure, inducement, influence or allurements and that the purposes of the above authority/donation and of all possible complications, side-effects, consequences and options have been explained to me before giving this authority or consent or both.

Signature of the Donor

FORM - 2
[See rule 4 (1)(b)]

I, Dr., possessing qualification of registered as medical practitioner at serial No. by the Medical Council, certify that I have examined Shri/Smt./Kum. s/o, d/o, w/o. aged whose free and informed consent about donation of the organ, namely to Shri/Smt./Kum. s/o, d/o, w/o. who is near relative of the donor and that the said donor is in proper state of health and is medically fit to be subjected to the procedure of organ removal.

Place.....
Dated.....

Signature

FORM - 3
[See rule 4 (1)(c)]

I, Dr. possessing qualification of registered as medical practitioner at Serial No. by the Medical Council, certify that Mr./Mrs. s/o, d/o, w/o. aged the donor, and Mr./Mrs. s/o, d/o, w/o. aged the recipient of the organ donated by the said donor are related to each other as brother/sister/mother/father/son/daughter as per their statement and the fact of this relationship has been established by the results of the tests for Antigenic Products of the Human Major Hysto-compatibility System, namely,, by the Authorisation Committee as per the information contained in their letter of approval No. dated

Place.....
Dated.....

Signature

FORM - 4
[See Rule 4(1)(d)]

I, Dr. possessing qualification of registered as medical practitioner at serial No.
by the Medical Council, certify that—

(i) Mr. s/o. aged resident of and Mrs. d/o,
w/o, aged resident of are related to each other as spouse according
to the statement given by them and their statement has been confirmed by means of following evidence before effecting the organ removal from the
body of the said Shri/Smt./Kum. (applicable only in the cases where considered necessary).

OR

(ii) The clinical condition of Shri/Smt. mentioned above is such that recording of his/her statement is not practicable.

Place
Dated

Signature of Regd. medical practitioner

FORM - 5
[See rule 4(2)(a)]

I, s/o, d/o, w/o,
aged resident of in the present of persons mentioned below hereby unequivocally authorise the removal
of my organ/organs, namely, from my body after my death for therapeutic purposes.

Signature of the Donor

Dated.....

(Signature)

1. Shri/Smt./Kum.
s/o, d/o, w/o
aged
resident

(Signature)

2. Shri/Smt./Kum.
s/o, d/o, w/o
aged
resident
is a near relative to the donor as

Dated.....

FORM - 6
[See rule 4(2)(B)]

I, s/o, d/o, w/o
aged resident of having lawful possession of the dead body of Shri/Smt./Kum.
..... s/o, d/o, w/o aged resident of
..... having known that the deceased has not expressed any objection to his/her organ/organs being
removed for therapeutic purposes after his/her death and also having reasons to believe that no near relative of the said deceased person has objection
to any of his/her organs being used for therapeutic purposes authorise removal of his/her body organs, namely,

Dated

Place

Signature

Person in lawful possession of the dead body.

Address
.....

FORM - 7
[See rule 4(2)(B)]

I, Mr./Mrs./Miss. having lawful possession of the dead body of Mr./Mrs./Miss.
son of/daughter of/wife of aged resident of after having
known that no objection was expressed by the deceased to any of his human organ being used after his death for therapeutic purposes and also having
reason to believe that no near relative of the deceased person has objection to any of the deceased person's organ being used for therapeutic purposes,
hereby authorise the removal of the deceased's organ, namely, for therapeutic purposes.

Signature.....

Name.....

Address.....
.....

Time and date.....

FORM - 8

[See rule 4(3)(a) and (b)]

We, the following members of the Board of medical experts after careful personal examination hereby certify that Shri/Smt./Kum. aged about son of/wife of/daughter of resident of is dead on account of permanent and irreversible cessation of all functions of the brain-stem. The tests carried out by us and the findings therein are recorded in the brain-stem death Certificate annexed hereto.

Dated:.....

Signature,.....

1. R. M. P., Incharge of the Hospital in which brain-stem death has occurred.

2. R. M. P. nominated from the panel of names approved by the Appropriate Authority.

3. Neurologist/Neuro-Surgeon nominated from the panel of names approved by the Appropriate Authority.

4. R. M. P. treating the aforesaid deceased person.

BRAIN-STEM DEATH CERTIFICATE

(A) PATIENT DETAILS:

1. Name of the patient
s.o./d.o./w.o.

Mr./Ms.
.....
Mr.
.....
Sex Age.....

2. Home Address
.....
.....
.....

3. Hospital Number,
.....
.....
.....

4. Name and Address of next of kin or person responsible for the patient (if none exists, this must be specified).
.....
.....
.....

5. Has the patient or next of kin agreed to any transplant?
.....
.....

6. Is this a Police Case?
Yes No.

(B) PRE-CONDITIONS:

1. Diagnosis: Did the patient suffer from any illness or accident that led to irreversible brain damage? Specify details

.....

.....

Date and time of accident/onset of illness

Date and onset of non-responsible coma

2. Findings of Board of Medical Experts:

- (1) The following reversible causes of coma have been excluded:
Intoxication (Alcohol)

Depressant Drugs

Relaxants (Neuromuscular blocking agents)

- Primary hypothermia

Hypovolaemic shock

Metabolic or endocrine disorders

Test for absence of brain-stem functions

First Medical Examination		Second Medical Examination	
1st	2nd	1st	2nd

(2) Coma

(3) Cessation of spontaneous breathing

(4) Pupillary size

(5) Pupillary light reflexes

(6) Doll's head eye movement

(7) Corneal reflexes (both eyes)

(8) Motor response in any cranial nerve distribution, any responses to stimulation of face, limb or trunk.

(9) Gag reflex

(10) Cough (Tracheal)

(11) Eye movements on coloric testing bilaterally

(12) Apnoea tests as specified

(13) Were any respiratory movements seen?

Date and time of first testing:

Date and time of second testing:

This is to certify that the patient has been carefully examined twice after an interval of about six hours and on the basis of findings recorded above,

Mr./Mrs. is declared brain-stem dead.

1. Medical Administrator Incharge of the hospital.

2. Authorised specialist.

3. Neurologist/Neuro-Surgeon.

4. Medical Officer treating the patient.

N. B. I. The minimum time interval between the first testing and second testing will be six hours.

II. No. 2 and No. 3 will be co-opted by the Administrator Incharge of the hospital from the Panel of experts approved by the appropriate authority.

FORM - 9
[See rule 4(3)(b)]

I, Mr./Mrs. son of/ wife of resident of hereby authorise removal of the organ/ organs, namely, for therapeutic purpose from the dead body of my son/daughter/Mr./Ms. aged whose brain-stem death has been duly certified in accordance with the law.

Signature:

Name:

Place

Date

FORM - 10

APPLICATION FOR APPROVAL FOR TRANSPLANTATION LIVE DONOR OTHER THAN NEAR RELATIVE

Whereas I s/o, d/o, w/o, l/o. aged residing at have been informed by my doctor that I am suffering from and may be benefitted by transplantation of into my body.

And whereas I s/o., d/o., w/o., aged residing at by reason of affection and attachment because:

.....

.....

..... (reason to be filled in)

would like to donate my to we and hereby apply to authorisation committee for permission for such transplantation to be carried out.

(donor) (recipient)

We solemnly affirm that the above decision has been taken without any undue pressure inclucement, influence or allurement and that all possible consequences and options of organ transplantation have been explained to us.

.....

Signature and address of prospective donor, Signature and address of prospective recipient,

FORM - 11

APPLICATION FOR REGISTRATION OF HOSPITAL TO CARRY OUT ORGAN TRANSPLANTATION

To

The Appropriate Authority for organ transplantation
(State Union Territory)

We hereby apply to be recognised as an institution to carry out organ transplantation. The required data about the facilities available in the hospital in the hospital are as follows:—

(A) HOSPITAL:

1. Name
2. Location
3. Govt./Pvt.
4. Teaching/Non-teaching
5. Approached by:

.....
.....
.....

Road:	Yes	No
Rail:	Yes	No
Air:	Yes	No

6. Total bed strength:
7. Name of the disciplines in the hospital
8. Annual budget
9. Patient turn-over/year

.....
.....
.....

(B) SURGICAL TEAM:

1. No. of beds
2. No. of permanent staff members with their designations
3. No. of temporary staff with their designations
4. No. of operations done per year
5. Trained persons available for transplantation (Please specify organ for transplantation)

.....
.....
.....
.....

(C) MEDICAL TEAM:

1. No. of beds
2. No. of permanent staff members with their designation
3. No. of temporary staff members with their designation
4. Patient turnover per year
5. No. of potential transplant candidates admitted per year

.....
.....
.....
.....

(D) ANAESTHESIOLOGY:

1. No. of permanent staff members with their designations
2. No. of temporary staff members with their designations
3. Name and No. of operations performed
4. Name and No. of equipments available
5. Total No. of operation theatres in the hospital
6. No. of emergency operation-theatres
7. No. of separate transplant operation theatre

.....
.....
.....
.....
.....
.....

(E) I.C.U./H.D.U. FACILITIES :

1. ICU/HDU facilities:
2. No. of I.C.U. beds
3. Trained: Nurses
Technicians
4. Name and No. of equipments in I.C.U.

Present Not present
.....
.....
.....

(F) OTHER SUPPORTIVE FACILITIES:

Data about facilities available in the hospital.

(G) LABORATORY FACILITIES:

1. No. of permanent staff with their designations
2. No. of temporary staff with their designations
3. Names of the investigations carried out in the Deptt.
4. Name and No. of equipments available

(H) IMAGING SERVICES:

1. No. of permanent staff with their designations
2. No. of temporary staff with their designations
3. Names of the investigations carried out in the Deptt.
4. Name and No. of equipments available.

(I) HAEMATOLOGY SERVICES:

- 1. No. of permanent staff with their designations
- 2. No. of temporary staff with their designations
- 3. Names of the investigations carried out in the Deptt.
- 4. Name and No. of equipments available

(J) BLOOD BANK FACILITIES:

Yes No

(K) DIALYSIS FACILITIES:

Yes No

(L) OTHER PERSONNEL:

- | | |
|--------------------|--------|
| 1. Nephrologist | Yes/No |
| 2. Neurologist | Yes/No |
| 3. Neuro-Surgeon | Yes/No |
| 4. Urologist | Yes/No |
| 5. G.I. Surgeon | Yes/No |
| 6. Paeditrician | Yes/No |
| 7. Physiotherapist | Yes/No |
| 8. Social Worker | Yes/No |
| 9. Immunologist | Yes/No |
| 10. Cardiologist | Yes/No |

The above said information is true to the best of my knowledge and I have no objection to any scrutiny of our facility by authorised personnel. A Bank Draft/Cheque of Rs. 1,000/- is being enclosed.

Sd/-
Head of the Institution

FORM - 12

CERTIFICATE OF REGISTRATION

This is to certify that Hospital located at has been inspected by the Appropriate and certificate of registration is granted for performing the organs transplantation of the following organs.

- 1.
- 2.
- 3.
- 4.

This certificate of registration is valid for a period of five years from the date of issue.

Signature

Signature

FORM - 13

[See sub- rule 8(2)]

OFFICE OF THE APPROPRIATE AUTHORITY

This is with reference to the application, datedfrom (Name of the hospital) for renewal of certificate of registration for preforming organ transplantation, under the Act.

After having considered the facilities and standards of the above-said hospital, the Appropriate Authority hereby renews the certificate of registration of the said hospital for the purpose of performing organ transplantatiin for a period of five years.

Appropriate Authority.....
Place.....
Date